



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0099]

Agency Information Collection Activities; Proposed Collection; Comment Request; Revision of the Requirements for Constituent Materials

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments regarding the requirement for the use of constituent materials in licensed biological products.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Revision of the Requirements for Constituent Materials in Biological Products--21 CFR

610.15(d) (OMB Control Number 0910-0666)--Extension

In the Federal Register of April 13, 2011 (76 FR 20513), FDA issued a final rule amending the regulation for the use of constituent materials in licensed biological products. Under 21 CFR 610.15(d), the Director of the Center for Biologics Evaluation and Research (CBER) or the Director of the Center for Drugs Evaluation and Research (CDER) may approve, as appropriate, a manufacturer's request for exceptions or alternatives to the regulation for constituent materials. Thus, the provision provides manufacturers of biological products with flexibility, as appropriate, to employ advances in science and technology as they become available, without diminishing public health protections. Manufacturers seeking approval of an exception or alternative must submit a request in writing. The request must be clearly identified with a brief statement describing the basis for the request and the supporting data. The request may be submitted as part of the original biologics application, as an amendment to the original, pending application or as a prior approval supplement to an approved application. The information to be collected assists FDA in identifying and reviewing requests for an exception or alternative to the requirements for constituent materials.

Respondents to this information collection provision are manufacturers of biological products. Since implementation of the final rule, FDA has received no submissions of requests for an exception or alternative for constituent materials. Therefore, FDA is estimating one

respondent and annual response annually to account for a possible submission to CBER or CDER of a request for an exception or alternative for constituent materials. The average burden per response is based on FDA experience with similar information collection requirements.

FDA estimates the burden of this collection of information as follows:

Table 1.—Estimated Annual Reporting Burden <sup>1</sup>					
21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
610.15	1	1	1	1	1

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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